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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,820	05/06/2002	Wolf-Georg Forssmann	P67431US0	8031

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,820	FORSSMANN ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 15-28 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 15 and 20, drawn to a serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the serine protease inhibitor according to claim 15 for preparing a medicament for the treatment of acute or chronic cervix inflammations, inflammation of Bartholin's glands and other processes accompanied by excessive formation of mucus and the resulting acute emergency situations, postoperative bleedings due to hyperfibrinolysis, and for the prophylaxis of lung emphysema formation in deficiencies of α1-proteinase inhibitor.

Group II, claim 16, drawn to a fragment of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino aid or a peptide with up to 100 amino acids, and X is SEQ ID NO:2.

Group III, claim 16, drawn to a fragment of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino aid or a peptide with up to 100 amino acids, and X is SEQ ID NO:3.

Group IV, claim 16, drawn to a fragment of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino aid or a peptide with up to 100 amino acids, and X is SEQ ID NO:4.

Group V, claim 16, drawn to a fragment of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino aid or a peptide with up to 100 amino acids, and X is SEQ ID NO:5.

Group VI, claim 16, drawn to a fragment of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino aid or a peptide with up to 100 amino acids, and X is SEQ ID NO:6.

Group VII, claims 17, 22 and 28, drawn to a nucleic acid (SEQ ID NO:7) coding for a serine protease inhibitor according to claim 15 and use of the nucleic acid for the preparation a medicament for use in gene therapy for the curing and prophylaxis of acute or chronic cervix inflammations, inflammation of Bartholin's glands and other processes accompanied by excessive formation of mucus and the resulting acute emergency situations, postoperative bleedings due to hyperfibrinolysis, and for the prophylaxis of lung emphysema formation in deficiencies of α1-proteinase inhibitor. Please note that SEQ ID NOS:8-12 do not code for a serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1.

Group VIII, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of asthma.

Group IX, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of AIDS.

Group X, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of pneumonia.

Group XI, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of tumor diseases and leukemia.

Group XII, claims 18-19 and 21, drawn to a medicament containing at least a nucleic acid coding for the serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of asthma.

Group XIII, claims 18-19 and 21, drawn to a medicament containing at least a nucleic acid coding for the serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of AIDS.

Group XIV, claims 18-19 and 21, drawn to a medicament containing at least a nucleic acid coding for the serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of pneumonia.

Group XV, claims 18-19 and 21, drawn to a medicament containing at least a nucleic acid coding for the serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and use of the medicament for the therapy of tumor diseases and leukemia.

Group XVI, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1 and a nucleic acid coding for the serine protease inhibitor, and use of the medicament for the therapy of asthma.

Group XVII, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1 and a nucleic acid coding for the serine protease inhibitor, and use of the medicament for the therapy of AIDS.

Group XVIII, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1 and a nucleic acid coding for the serine protease inhibitor, and use of the medicament for the therapy of pneumonia.

Group XIX, claims 18-19 and 21, drawn to a medicament containing at least one serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1 and a nucleic acid coding for the serine protease inhibitor, and use of the medicament for the therapy of tumor diseases and leukemia.

Group XX, claims 23 and 25, drawn to antibodies or antibody fragments against epitopes of a serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, and a diagnostic agent containing the same.

Group XXI, claims 23, 26-27, drawn to antibodies or antibody fragments against epitopes of a serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1, a medicament containing the same, and use of the same for preparing a medicament for the treatment of diseases involving too high an expression of the serine protease inhibitor or too high an activity of the regions coding for the serine protease inhibitor.

Group XXII, claim 24, drawn to poly- or oligonucleotides which will hybridize to regions of the cDNA or corresponding RNA under stringent conditions and optionally prevent the expression of coding regions of the genes coding for a serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature linking Groups I to XXII appear to be that they all relate to a serine protease inhibitor having the amino acid sequence according to SEQ ID NO:1 or its fragments.

However, an encoded serine protease inhibitor having the same amino acid sequence of SEQ ID NO:1 has been submitted to the EMBL/GenBank/DDBJ databases on March 10, 1998 and April 06, 1999 (see EMBL DATABASES Accession No. AJ228139, XP2131450, IDS).

Therefore, the technical feature linking the inventions of Groups I to XXII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Consequently, the claimed subject matter was broken up into the aforementioned Groups of Inventions. The inventions are distinct, each from the others for the following reasons.

The serine protease inhibitor having the amino acid sequence of SEQ ID NO:1 of Group I is chemically or biologically different from any fragment of the serine protease inhibitor having the amino acid sequence R1-X-R2, wherein X is SEQ ID NOs: 2 to 6 of Groups II to VI, respectively, or a nucleic acid (made up of nucleotides rather amino acid residues) of SEQ ID NO:7 of Group VII, or a medicament containing at least one serine protease inhibitor having the amino acid sequence of SEQ ID NO:1 of Groups VIII to XII, or a medicament containing at least a nucleic acid coding for the serine protease inhibitor having the amino acid sequence of SEQ ID NO:1 of Groups XIII to XV, or a medicament containing at least one serine protease inhibitor having the amino acid sequence of SEQ ID NO:1 **and** a nucleic acid coding for the same of Groups XVI to XIX, or antibodies or antibody fragments against epitopes of a serine protease inhibitor having the amino acid sequence of SEQ ID NO:1 of Groups XX to XXI, or poly- or oligonucleotides which will hybridize to the cDNA or corresponding RNA of Group XXII.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT, and the inventions are distinct for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Quang Nguyen, Ph.D.

DAVID GUZO
PRIMARY EXAMINER